FORM PTO-1390
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY DOCKET NUMBER
ADMS-0003

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)
10/031860

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IB00/00530	**26 April 2000**	**29 April 1999**

TITLE OF INVENTION **Device For Depositing a Non-Flowable Object or a Non-Flowable Medicament in a Body Cavity**

APPLICANT(S) FOR DO/EO/US **Peter James Brian LAMB**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. X This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. _ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. X This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. X A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. _ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. X has been transmitted by the International Bureau.
   c. _ is not required, as the application was filed in the United States Receiving Office (RO/US)
6. _ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

7. X Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. _ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. _ have been transmitted by the International Bureau.
   c. _ have not been made; however, the time limit for making such amendments has NOT expired.
   d. X have not been made and will not be made.

8. _ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. X An oath or declaration of the inventor(s) 35 U.S.C. 371(c)(4). (Unsigned)

10. _ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. _ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

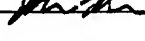
12. _ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. X A FIRST preliminary amendment.
    _ A SECOND or SUBSEQUENT preliminary amendment.

14. _ A substitute specification.

15. _ A change of power of attorney and/or address letter.

16. X Other items or information:
    Specification and claims as amended under Article 34; Preliminary Examination Report

EXPRESS MAIL Mailing Label No. **EL899365394US**
Date of Deposit: **29 October 2001**
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231
MAILER **John Hill**
SIGNATURE 

531 Rec'd PCT/PTC 29 OCT 2001

U.S. APPLICATION NO. (if known, 37 C.F.R. 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY DOCKET NUMBER
Not yet known 10/031860	PCT/IB00/00530	ADMS-0003

17. X The following fees are submitted:

Basic National Fee (37 CFR 1.492(a)(1) - (5)):

Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO.....**$1,040.00**

International preliminary examination fee (37 CFR 1.482 not paid to USPTO but International Search Report has been prepared by the EPO or JPO.....**$890.00**

International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....**$740.00**

International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4).....**$710.00**

International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4).....**$100.00**

	CALCULATIONS	PTO USE ONLY
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 890.00	
Surcharge of $130.00 for furnishing the oath or declaration later that _ 20 X 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00	

Claims	Number Filed	Number Extra	Rate		
Total claims	15 - 20 = 0	0	X $18.00	$ 0	
Independent Claims	3 - 3 = 0	0	x $84.00	$ 0	
Multiple dependent claims(s) (if applicable)			+ $280.00	$ 0	
TOTAL OF ABOVE CALCULATIONS =				$ 1,020.00	
X Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½.				$ - 510.00	
SUBTOTAL =				$ 510.00	
Processing fee of **$130.00** for furnishing the English translation later the _ 20 _30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$ 0	
TOTAL NATIONAL FEE =				$ 510.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property			+	0	
TOTAL FEES ENCLOSED =				$ 510.00	
				Amount to be: refunded	$
				charged	$

a. X A check in the amount of $ 510.00 to cover the above fee is enclosed.

b. _ Please charge my Deposit Account No. 23-3050 in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. X The Commissioner if hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23-3050. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

David A. Cherry, Esq.
Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

SIGNATURE

David A. Cherry, Esq.
NAME

35,099
REGISTRATION NUMBER

DOCKET NO. ADMS-0003 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Peter James Brian LAMB

International Filing Date: 26 April 2000

Group Art Unit: not yet assigned

International Appln. No. : PCT/IB00/00530

Examiner: not yet assigned

For: DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY

Assistant Commissioner
for Patents
Washington, D.C. 20231

Dear Sir:

PRELIMINARY AMENDMENT

Prior to examination, please amend this application as follows:

In the Claims:

Please amend claims 4, 5, 7, 8, and 11-14, and cancel claims 16 and 17 without prejudice, as shown in the attached *"Marked-Up Version of Claims, Showing All Changes"* such that the claims, in clean form, recite as follows:

1. A device for use by a female user to self-deposit a non-flowable object or a non-flowable medicament in her vagina, the device including

an elongate body which includes a gripping portion and an elongate barrel extending from the gripping portion, with a passage, configured to receive a non-flowble object or medicament, extending through the body, the passage having an outlet at a free end

of the barrel and a portion of the passage, located in the gripping portion, being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

2. A device for use by a female user to self-deposit a non-flowable object or a non flowable medicament in her vagina, the device including

an elongate body which includes an elongate barrel which is penile-shaped or roughly triangular in cross section with a passage, configured to received a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

3. A tampon insertion device which includes

an elongate body which includes an elongate barrel with a passage, configured to receive a tampon, extending through the body, the passage having an outlet at a free end of the barrel and a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced along the passage to push a tampon received in the passage out of the passage through the outlet thereof.

4. A device as claimed in claim 1, in which the barrel is penile-shaped at least in cross section, being roughly triangular in cross section.

5. A device as claimed in claim 1, in which the passage has an inlet remote from its outlet and in which the curved portion of the passage renders a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle of between 170° and 135° relative to each other.

6. A device as claimed in claim 5, in which the obtuse angle between the axes is between 160° and 140°.

7. A device as claimed in claim 1, in which an outlet end portion of the barrel has the general shape, or incorporates at least some of the design features of a glans penis.

8. A device as claimed in claim 1, in which the passage includes a medicament or object chamber for receiving the non-flowable medicament or object.

9. A device as claimed in claim 8, in which the chamber is spaced from the outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a vagina, thus at least partially closing off the outlet whilst the barrel is being inserted into the vagina and preventing the object or medicament from scraping against or injuring body tissue material.

10. A device as claimed in claim 3, in which the barrel includes a longitudinally extending slit through which a string of a tampon received in the passage can protrude.

11. A device as claimed in claim 1, in which at least the barrel is of a material having a Shore A hardness between 40 and 80.

12. A device as claimed in claim 1, in which the body and the ejector or plunger are manufactured from paper or paper pulp, rending the device disposable.

13. A device as claimed in claim 1, in which the body defines gripping surfaces such that the body can be gripped between a thumb, an index finger and a middle finger of one hand of a user, the gripping surfaces being arranged such that when the body is being held between the three fingers, with the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between 45° and 10°.

14. A device as claimed in claim 1, in which the body is a monolithic, integrally moulded body.

15. A device as claimed in claim 3, in which a part of the barrel, above the outlet, and a part of the barrel, below the outlet, are displaceable towards each other, allowing the parts to be displaced or forced towards each other when the barrel is being inserted into a vagina, thus at least partially closing off the outlet whilst the barrel is being inserted into the vagina and preventing the tampon from scraping against or injuring body tissue material.

Conclusion

Applicant requests consideration and allowance of the pending claims. Should the Examiner have any comments, Applicant urges the Examiner to call the undersigned at the indicated phone number.

Respectfully submitted,

David A. Cherry
Registration No. 35,099

Date: October 29, 2001

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Marked-Up Version, Showing All Changes

In the Claims:

Please amend claims 4, 5, 7, 8, and 11-14, and cancel claims 16 and 17 without prejudice, as shown:

4. A device as claimed in claim 1 [or claim 3], in which the barrel is penile-shaped at least in cross section, being roughly triangular in cross section.

5. A device as claimed in [any one of the preceding claims] claim 1, in which the passage has an inlet remote from its outlet and in which the curved portion of the passage renders a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle of between 170° and 135° relative to each other.

7. A device as claimed in [any one of the preceding claims] claim 1, in which an outlet end portion of the barrel has the general shape, or incorporates at least some of the design features of a glans penis.

8. A device as claimed in claim 1 [or claim 2], in which the passage includes a medicament or object chamber for receiving the non-flowable medicament or object.

11. A device as claimed in [any one of the preceding claims] claim 1, in which at least the barrel is of a material having a Shore A hardness between 40 and 80.

12. A device as claimed in [any one of claims 1 to 10 inclusive] claim 1, in which the body and the ejector or plunger are manufactured from paper or paper pulp, rending the device disposable.

13. A device as claimed in [any one of the preceding claims] claim 1, in which the body defines gripping surfaces such that the body can be gripped between a thumb, an index finger and a middle finger of one hand of a user, the gripping surfaces being arranged such that when the body is being held between the three fingers, with the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between 45° and 10°.

14. A device as claimed in [any one of the preceding claims] claim 1, in which the body is a monolithic, integrally moulded body.

[16. A device as claimed in claim 1 or claim 2 or claim 3, substantially as herein described and illustrated.

17. A new device, substantially as herein described.]

DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY

THIS INVENTION relates to a device for depositing a non-flowable object or a non-flowable medicament in a body cavity.

Various conventional devices for depositing a non-flowable medicament or object, such as a tablet in body cavities, such as the vagina and rectum, exist. Typically, these conventional devices comprise a blunt, straight, hollow tube or barrel into which a plunger or piston or ejector can be inserted from one end, with a medicament or object chamber being provided at an opposed end. GB 2 033 754 provides an example of such a device for inserting a sanitary tampon. The device of GB 2 033 754 includes a linear, circular cylindrical barrel with a blunt, rounded outlet end. DE 522 404 discloses an instrument for the introduction of radium needles into body orifices or tissue. The instrument of DE 522 404 may include a curved or bent barrel with the curvature being located between an outlet of the barrel and a gripping portion of the device. However, the device of DE 522 404 is not suitable for the self-introduction of non-flowable medicaments such as tablets, capsules, suppositories, pills, bougies, or the like in the vagina of a female user, nor is it suitable for the self-insertion of a tampon in the vagina of a female user.

All of the conventional devices suffer from at least some of the following problems: The conventional device is of a hard and non-pliable material so there is no bend or give during insertion of the device into a vagina. This rigidity makes vaginal insertion more difficult and painful. Often women do not know that the vagina is angled upwards from its opening and that it is not horizontal. After inserting a leading end of the conventional device through the vaginal opening in the horizontal direction, the leading end collides with the back wall of the vagina, which is painful and causes the user to think that the device has reached the limit of the vagina. The user then deposits the medicament or object at a too shallow depth in the vagina. No stop guard is provided to limit the depth of insertion of the conventional devices into the vagina. If the device is inserted to the full depth of the vagina and collides with the vaginal vault, considerable pain is caused. This lack of depth control is particularly hazardous in the case of a pregnant woman. Some conventional devices have leading ends which flare outwards which make them even more difficult to insert into a vagina. Conventional devices can only comfortably be inserted into a vagina when the woman is lying on her back with her knees flexed. It is difficult to insert conventional devices which are often difficult to grip and difficult to control when being inserted into a vagina.

It is an object of this invention to provide means which alleviate at least some of these problems.

According to a first aspect of the invention, there is provided a device for use by a female user to self-deposit a non-flowable object or a non-flowable medicament in her vagina, the device including

an elongate body which includes a gripping portion and an elongate barrel extending from the gripping portion, with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel and a portion of the passage, located in the gripping portion, being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

According to a second aspect of the invention, there is provided a tampon insertion device which includes

an elongate body which includes an elongate barrel with a passage, configured to receive a tampon, extending through the body, the passage having an outlet at a free end of the barrel and a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced along the passage to push a tampon received in the passage out of the passage through the outlet thereof.

The barrel may be penile-shaped at least in cross section.

According to a third aspect of the invention, there is provided a device for use by a female user to self-deposit a non-flowable object or a non-flowable medicament in her vagina, the device including

an elongate body which includes an elongate barrel which is penile-shaped or roughly triangular in cross section with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

In this specification, the term "non-flowable medicament" is intended to include tablets, capsules, suppositories, pills, bougies, or the like.

The passage is typically round or circular in cross-section.

The passage may have an inlet remote from its outlet. The curved portion of the passage may render a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle relative to each other. The obtuse angle may be between 170° and 135.° Preferably, the obtuse angle is between 160° and 140°, and most preferably between 155° and 145°, and is thus selected to correct for vaginal inclination.

The body of the device according to the second and third aspects of the invention may also include a gripping portion from which the barrel extends. The inlet of the passage may thus be in the gripping portion, which may be thickened compared to the barrel, thus also functioning in use as a stop formation, limiting the length of the body of the device which may be introduced into a body cavity.

The curved portion of the passage of the device according to the second and third aspects of the invention is also typically located in the gripping portion of the body, so that the portion of the passage in the barrel is typically linear, allowing at least a portion of the barrel to be straight. Preferably, the entire barrel is straight, which is an advantage, since the human vagina is straight and not curved.

An outlet end portion of the barrel may have the general shape or may incorporate at least some of the design features of a glans penis. Thus, the barrel may have a rounded point which flares back like the corona of a glans penis and which in use lifts the opposing vaginal walls apart when the barrel is inserted into a vagina by a wedging action. The roughly triangular cross-section of the barrel, similar to that of a penis, allows the smallest area of contact or friction with a posterior vaginal wall. Side walls of the barrel are thus in use angled away from lateral walls of the vagina, with a relatively broad superior wall of the barrel being stabilized by low pressure contact with the anterior vaginal wall.

The ejector or plunger may have a flexible rod, allowing the rod to bend to follow the curvature of the passage when it is displaced along the passage. The rod may be of a synthetic plastics or polymeric material, such as polypropylene or the like.

The passage may include a medicament or object chamber for receiving the non-flowable medicament or object. The chamber may be spaced from the outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a body cavity, thus at least partially closing off the outlet whilst the barrel is being inserted into the body cavity and preventing the objet or medicament from scraping against or injuring body tissue material, such as the vaginal mucosa.

At least the barrel may be of a material having a Shore A hardness between 40 and 80, e.g. 70. Thus, the barrel may be of a synthetic plastics or polymeric material, such as silicone rubber, having a suitable hardness. The gripping portion may be of a thermoplastic material, with the barrel and the gripping portion being moulded or fused together. Instead, the barrel and the gripping portion may be fitted together by other means, such as glue or mechanical attachment means or combi moulding, thus advantageously allowing the gripping portion to be of a thermoplastic material which has a lower maximum working temperature than the moulding temperature of the material of which the barrel is formed, and which may thus be cheaper. In another embodiment of the invention, the gripping portion and the barrel may both be of the same synthetic or polymeric plastics material, e.g. silicone rubber, the body of the device thus being monolithic and integrally moulded. Instead, the body and the ejector or plunger may be manufactured from paper or paper pulp, rendering the device disposable. The material may be selected to be biodegradable or to allow the device to be flushed safely down a toilet.

The barrel may have a length of between 60mm and 100mm, e.g. 70mm and a maximum external diameter of between 10mm and 20mm, e.g. 17mm, when the device is intended for a non-flowable medicament.

The outlet of the passage may be in the form of a slit extending between opposed sides of the barrel and may be located on the longitudinal axis of the barrel.

The body may define gripping surfaces such that the body can be gripped between a thumb, and index finger and a middle finger of one hand of a user. The gripping surfaces may be arranged such that when the body is being held between the tree fingers, with the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between 45 ° and 10 °.

The passage may be shaped and dimensioned to receive a tampon. The barrel may thus include a longitudinally extending slit through which a string of the tampon received in the passage can protrude.

In one embodiment of the invention, the slit may extend from the outlet and may form a right angle at an end of a longitudinally extending portion thereof remote from the outlet to extend transversely across an upper surface of the barrel. An upper front portion of the barrel is thereby rendered displaceable in flip top fashion. This allows insertion of a solid object such as a tampon into the barrel from above, without having to feed the solid object into the barrel through the outlet.

The ejector or plunger may include a thumb grip at a free end of its rod, the gripping portion of the body defining a recess for the thumb grip so that

almost all of the ejector or plunger can be received inside the body of the device when the ejector or plunger is pushed as far into the passage as it can go.

The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings in which

Figure 1 is a sectioned side view of an embodiment of a device in accordance with the invention for depositing a non-flowable medicament in a body cavity;

Figure 2 is a top plan view of the device of Figure 1;

Figure 3 is a bottom plan view of the device of Figure 1;

Figure 4 is a front end view of the device of Figure 1;

Figure 5 is a rear end view of the device of Figure 1;

Figure 6 is a sectioned side view of another embodiment of a device in accordance with the invention for depositing a non-flowable medicament or a non-flowable object in a body cavity;

Figure 7 is a top plan view of the device of Figure 6;

Figure 8 is a bottom plan view of the device of Figure 6;

Figure 9 is a front end view of the device of Figure 6; and

Figure 10 is a rear end view of the device of Figure 6.

Referring to Figures 1 to 5 of the drawings, reference numeral 10 generally indicates an embodiment of a device in accordance with the invention for depositing a non-flowable medicament or object in a body cavity, such as a vagina. The device 10 includes an elongate monolithic body 12 which comprises an elongate barrel 14 and a gripping portion 16 from which the barrel 14 extends.

The barrel 14 and the gripping portion 16 are integrally moulded from a synthetic plastics or polymeric material such as a silicone rubber and has a Shore A hardness of about 70. A passage 18 extends through the gripping portion 16 and the barrel 14. The passage 18 has an inlet 20 in the gripping

portion 16 and an outlet 22 at a free end of the barrel 14, remote from the gripping portion 16. A portion of the passage 18 between the inlet and the outlet and located in the gripping portion 16, is curved in side view, as can be clearly seen in Figure 1 of the drawings. The passage 18 is round in cross-section.

The curved portion of the passage 18 between its inlet 20 and its outlet 22 renders a centrally disposed longitudinal axis 24 of the barrel 14 and a centrally disposed axis 26 through the inlet 20 of the passage 18, at an obtuse angle of 150° relative to each other (see Figure 1), and this angle thus matches the angle of inclination of the vagina of a standing woman relative to the horizontal.

The barrel 14 is generally penile shaped and is thus roughly triangular in cross-section, similar to the cross section of a penis. More accurately, a cross-sectional outline of the barrel 14 falls on the outline of a triangle. An outlet end portion 28 of the barrel 14, remote from the gripping portion 16, generally has the shape of a glans penis. A bottom surface of the end portion 28 has a sled-like curve in side view to inhibit abrasion of the posterior vaginal wall in use. The barrel 14 thus has a rounded point which flares back like the corona of a glans penis and which in use lifts and wedges the opposing vaginal walls apart when the barrel 14 is inserted into a vagina.

The outlet 22 of the passage 18 is in the form of a slit extending between opposed sides of the barrel 14 and is located in an upper half of the outlet end portion 28, to avoid scraping vaginal exudate into the outlet 22 during insertion of the barrel 14 into a vagina in use.

The device 10 includes a piston or ejector or plunger 30 which can be displaced along the passage 18 and which includes a flexible rod 32 of polypropylene. The rod 32 is thus able to follow the curvature of the passage 18 when the plunger 30 is displaced along the passage 18. The plunger 30 includes

an ergonometrically designed thumb grip 34 at a free end of the flexible rod 32. As can be clearly seen in Figure 1 of the drawings, the gripping portion 16 of the body 12 defines a recess 36 for the thumb grip 34 so that almost all of the plunger 30 can be received inside the body 12 when the plunger 30 is pushed as far into the passage 18 as it can go.

The passage 18 includes or defines a medicament or object chamber 38 (see Figure 1) for receiving the non-flowable medicament or non-flowable object. The chamber 38 is spaced from the outlet 22 of the passage and is in the form of a widening of the passage 18 tailored to receive a tablet or capsule or tampon or the like.

Roughened and depressed gripping surfaces 40 are provided on an external top surface and an external bottom surface of the gripping portion 16 of the body 12.

The barrel 14 is approximately 70mm long and has a maximum external diameter of about 17mm.

The device 10 is particularly, though not necessarily exclusively suitable for depositing a non-flowable medicament, such as a tablet or capsule, in a vagina. In use, the ejector or plunger 30 is withdrawn from the passage 18 at least far enough so that it does not protrude into the chamber 38, as shown in Figure 1 of the drawings, and the non-flowable medicament is placed inside the medicament chamber by inserting it through the outlet 22. The barrel 14 is then inserted into a body cavity, such as the vagina of a human female until the gripping portion 16 limits the part or length of the body 12 of the device 10 which can be introduced into the vagina. Thus, the gripping portion 16 also functions in use as a stop formation. The gripping portion 16 affords a large comfortable grip for the hand of the person inserting the barrel 14 into the vagina.

As will be appreciated, since the body 12 is of a silicone rubber and thus quite flexible, a part or upper lip 42 of the barrel 14, above the outlet 22, and a part or lower lip 44 of the barrel 14, below the outlet 22 are displaced or forced towards each other whilst the barrel 14 is being inserted into the vagina. Thus, the outlet 22 is closed off whilst the barrel 14 is being inserted into the vagina, inhibiting intrusion of vaginal exudate into the passage 18 through the outlet 22. The flexibility of the lips 42, 44 also allows for easy insertion of the non-flowable medicament into the chamber 38 and prevents abrasion or injury to the vaginal mucosa by a sharp-edged non-flowable medicament, e.g. a vaginal tablet.

By enlarging the barrel 14 and the chamber 38, the device 10 can also easily be adapted for use in inserting a tampon in a vagina. Typically, in such a case, the barrel 14 will include a longitudinally extending slit through which a string of the tampon can protrude.

When the barrel 14 is fully inserted into the vagina, the ejector or plunger 30 is pushed into the body 12 as far as it can go, forcing the non-flowable medicament or solid object out of the chamber 38, through the outlet 22, and thus depositing the non-flowable medicament or object in the vagina. The barrel 14 is then withdrawn from the vagina.

Referring to Figures 6 to 10 of the drawings, reference numeral 100 generally indicates another embodiment of a device in accordance with the invention for depositing a solid object, such as a non-flowable medicament or a non-flowable object, in a body cavity, such as a vagina. The device 100 is similar to the device 10, and unless otherwise indicated, the same parts or features are indicated by the same reference numerals used in relation to the device 10.

The body 12 of the device 100 is of Krayton G 2705 material having a Shore A hardness of 55. The ejector or plunger 30 is of the same material.

Unlike the outlet 22 of the device 10, the outlet 22 of the device 100 is located on a central longitudinal axis of the barrel 14 (not shown). Also unlike the device 10, the gripping portion 16 of the body 12 of the device 100 does not define a recess which can accommodate the thumb grip 34. Instead, when the ejector or plunger 30 is inserted fully into the passage 18, the thumb grip 34 abuts an end of the body 12 remote from the outlet 22.

The device 100 has a semi-circular 0.5 mm deep groove 102 in the upper lip 42 of the barrel 14. This facilitates bending of the upper lip 42 towards the lower lip 44 during insertion of the barrel 14 into a vagina thereby to close the outlet 22 off whilst the barrel 14 is being inserted into the body cavity. The groove 102 also facilitates the passage of a solid non-flowable object from the chamber 38 out through the outlet 22, by allowing the upper lip 42 to move away from the lower lip 44.

The device 100 is used in similar fashion to the device 10. It is to appreciated that, when the body 16 is gripped between a thumb, an index finger and a middle finger of one hand of a user, with the thumb touching the upper gripping surface 40 and the index finger and middle finger touching the lower gripping surface 40, and with areas on the lower surface 40 touched by the middle finger and the index finger being orientated such that they are in the same horizontal plane, the barrel 14 projects upwardly away from the horizontal plane at an angle of about 30 °. If a woman holds the device 100 such that said areas touched by the middle and index finger are in line at an angle of about 120 ° to the horizontal, which is a natural holding position, the barrel 14 projects upwardly at an angle of about 150 ° relative to the horizontal, which is the angle of inclination of the vagina of a standing woman relative to the horizontal, as hereinbefore mentioned.

The Applicant believes that the device 10, 100 as illustrated, and particularly when intended to deposit a non-flowable medicament such as a capsule or tablet, or a solid object such as a tampon, in a vagina, has the following advantages;

The length of the barrel 14 is not intimidating, but nonetheless provides effective depth of deposition of the non-flowable medicament or the object. The barrel 14 is of a relatively soft, elastic material which is less difficult and painful to insert than the barrel of conventional devices. The material is easier for the fingers to grip securely and the grippability of the device is further improved by the gripping surfaces 40. The generally triangular, penile-like cross-section of the barrel 14 (see Figure 4) is easier and more comfortable to insert into a vagina. Friction against the back vaginal wall is reduced.

The angular arrangement of the barrel 14 relative to the inlet 20 of the passage 18 promotes easier advancement of the barrel 14 up the vagina. There is a built-in correction for the direction or inclination of the vaginal cavity, which causes less damage and discomfort to the user. The barrel 14 can be inserted whilst the user is sitting or standing and the procedure is therefor much easier and more comfortable to accomplish physically and much less an affront to a female's dignity.

The glans penis-like outlet end portion 28 of the barrel 14 of the device 10 is easier and more comfortable to insert than the leading end portions of conventional devices. The shape and location of the outlet 22 of the barrel 14 provides for better hygiene and promotes comfort when the barrel 14 is inserted into the vagina, by eliminating any scraping effect on the back wall of the vagina.

The thickened gripping portion 16 ensures automatic depth control when the barrel 14 is inserted into a vagina.

The integrally moulded design of the gripping portion 16 and the barrel 14 provides the device 10, 100 with a degree of flexibility, which enhances comfort and ease when the barrel 14 is inserted into a vagina.

The gripping portion 16 provides a large comfortable handle for the device 10. It affords a secure grip and therefor better control of the device 10 during insertion of the barrel 14 into the vagina.

CLAIMS:

1. A device for use by a female user to self-deposit a non-flowable object or a non-flowable medicament in her vagina, the device including

an elongate body which includes a gripping portion and an elongate barrel extending from the gripping portion, with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel and a portion of the passage, located in the gripping portion, being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

2. A device for use by a female user to self-deposit a non-flowable object or a non-flowable medicament in her vagina, the device including

an elongate body which includes an elongate barrel which is penile-shaped or roughly triangular in cross section with a passage, configured to receive a non-flowable object or medicament, extending through the body, the passage having an outlet at a free end of the barrel, a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced by the user along the passage to push a non-flowable object or medicament received in the passage out of the passage through the outlet thereof into the vagina of the user.

3. A tampon insertion device which includes

an elongate body which includes an elongate barrel with a passage, configured to receive a tampon, extending through the body, the passage having an outlet at a free end of the barrel and a portion of the passage spaced from the outlet being curved in the longitudinal direction of the passage; and

an ejector or plunger which can be displaced along the passage to push a tampon received in the passage out of the passage through the outlet thereof.

4. A device as claimed in claim 1 or claim 3, in which the barrel is penile-shaped at least in cross section, being roughly triangular in cross section.

5. A device as claimed in any one of the preceding claims, in which the passage has an inlet remote from its outlet and in which the curved portion of the passage renders a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage at an obtuse angle of between 170 ° and 135 ° relative to each other.

6. A device as claimed in claim 5, in which the obtuse angle between the axes is between 160 ° and 140 °.

7. A device as claimed in any one of the preceding claims, in which an outlet end portion of the barrel has the general shape, or incorporates at least some of the design features of a glans penis.

8. A device as claimed in claim 1 or claim 2, in which the passage includes a medicament or object chamber for receiving the non-flowable medicament or object.

9. A device as claimed in claim 8, in which the chamber is spaced from the outlet of the passage, allowing a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaced or forced towards each other when the barrel is being inserted into a vagina, thus at least partially closing off the outlet whilst the barrel is being inserted into the vagina and preventing the object or medicament from scraping against or injuring body tissue material.

10. A device as claimed in claim 3, in which the barrel includes a longitudinally extending slit through which a string of a tampon received in the passage can protrude.

11. A device as claimed in any one of the preceding claims, in which at least the barrel is of a material having a Shore A hardness between 40 and 80.

12. A device as claimed in any one of claims 1 to 10 inclusive, in which the body and the ejector or plunger are manufactured from paper or paper pulp, rendering the device disposable.

13. A device as claimed in any one of the preceding claims, in which the body defines gripping surfaces such that the body can be gripped between a thumb, an index finger and a middle finger of one hand of a user, the gripping surfaces being arranged such that when the body is being held between the three fingers, with the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between 45 ° and 10 °.

14. A device as claimed in any one of the preceding claims, in which the body is a monolithic, integrally moulded body.

15. A device as claimed in claim 3, in which a part of the barrel, above the outlet, and a part of the barrel, below the outlet, are displaceable towards each other, allowing the parts to be displaced or forced towards each other when the barrel is being inserted into a vagina, thus at least partially closing off the outlet whilst the barrel is being inserted into the vagina and preventing the tampon from scraping against or injuring body tissue material.

16. A device as claimed in claim 1 or claim 2 or claim 3, substantially as herein described and illustrated.

17. A new device, substantially as herein described.

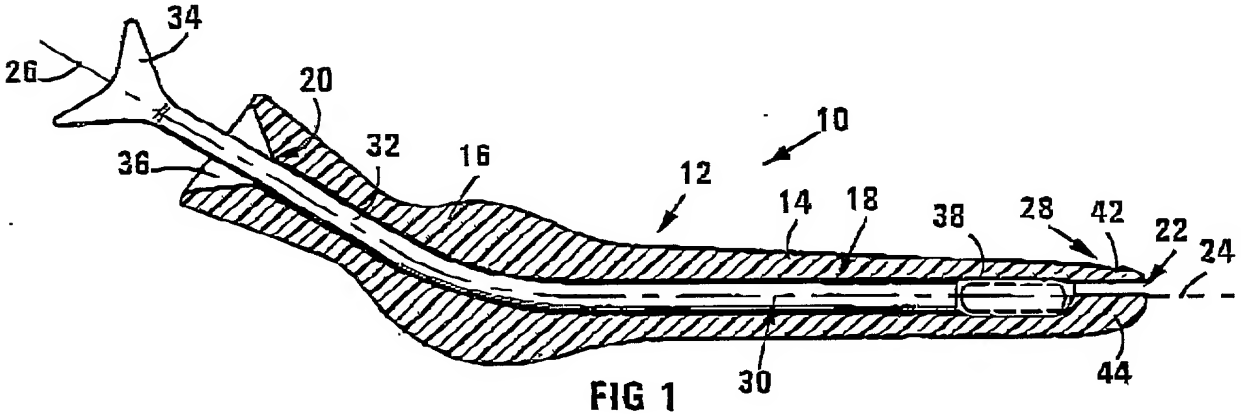


FIG 1

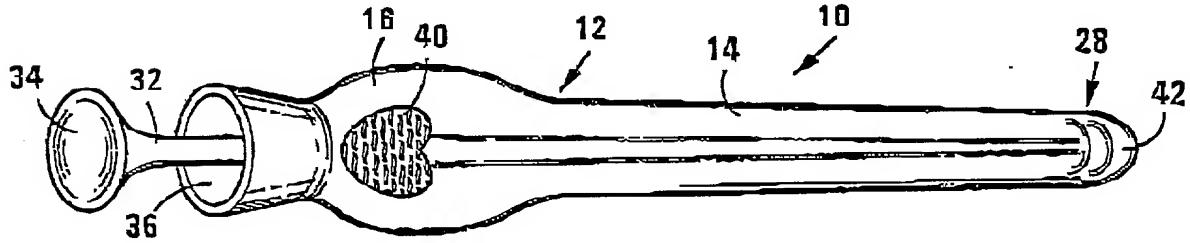


FIG 2

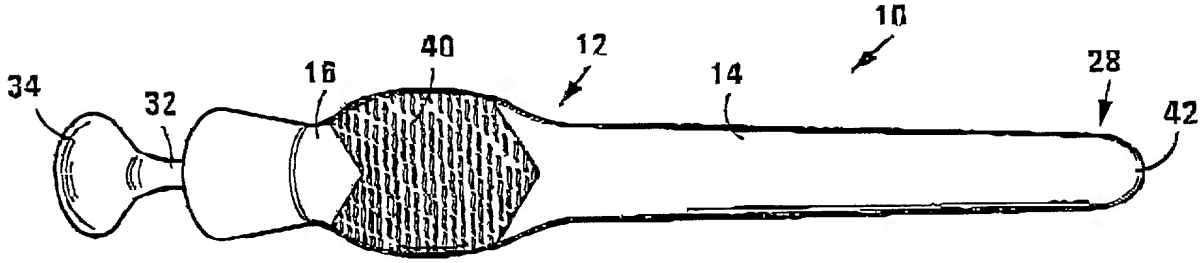


FIG 3

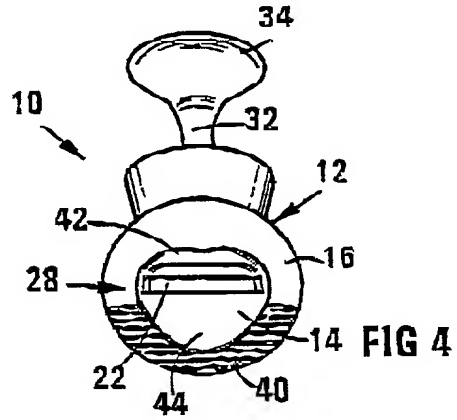


FIG 4

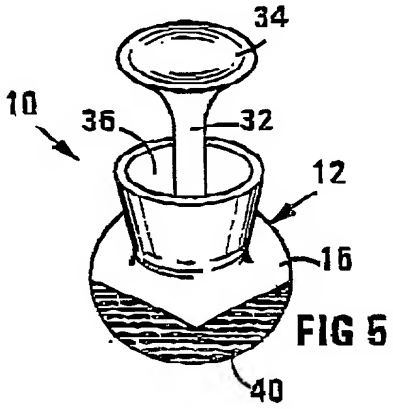


FIG 5

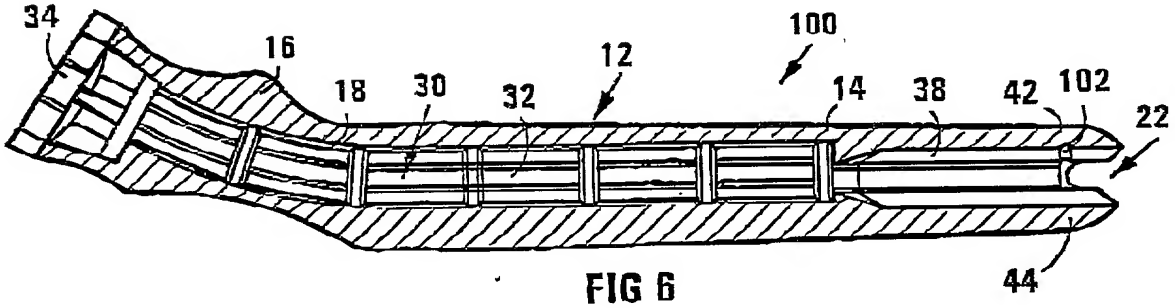


FIG 6

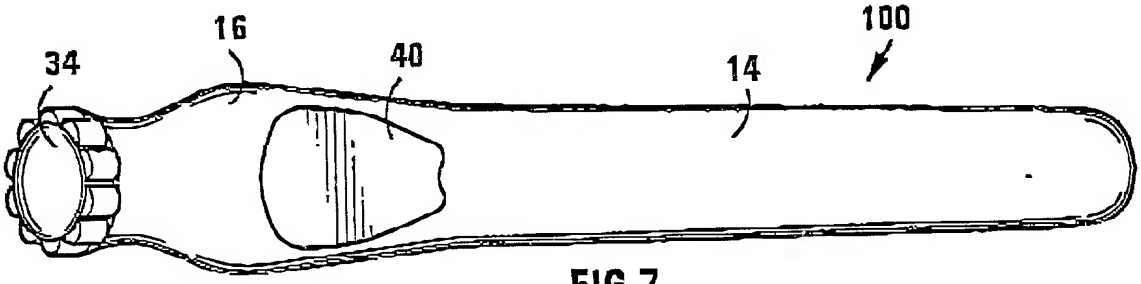


FIG 7

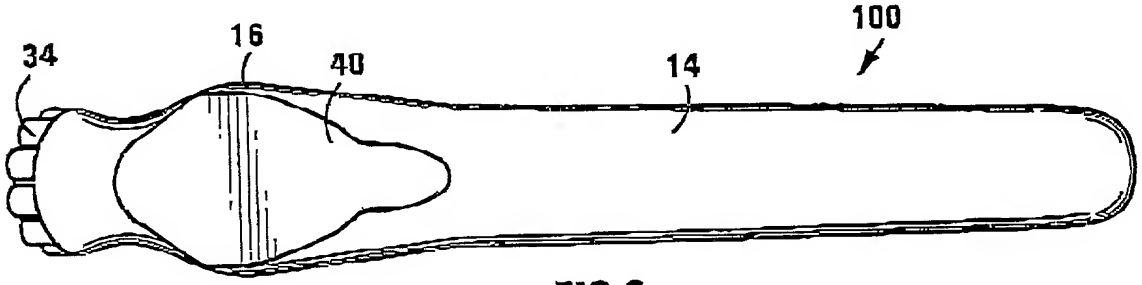


FIG 8

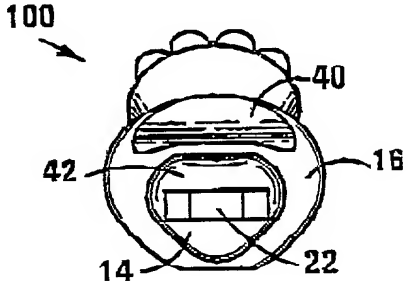


FIG 9

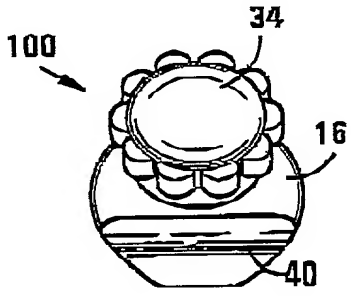


FIG 10

DOCKET NO. ADMS-0003 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Peter James Brian Lamb

Group Art Unit: not yet known

Intl. Appln. No.: PCT/IB00/00530

Examiner: not yet assigned

Intl. Filing Date: 26 April 2000

For: DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a

☒ Utility Patent ☐ Design Patent

is sought on the invention, whose title appears above, the specification of which:

☐ is attached hereto.

☒ was filed on 26 April 2000 as International Application No. PCT/IB00/00530 .

☒ said application having been amended on 14 June 2001 .

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a-d) of any **foreign application(s)** for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of any application on which priority is claimed:

Priority Claimed (If X'd)	Country	Serial Number	Date Filed
☒	South Africa	99/3006	29 April 1999
☐			
☐			
☐			

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Serial Number	Date Filed	Patented/Pending/Abandoned

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Serial Number	**Date Filed**
____________________	______________
____________________	______________

I hereby appoint the following persons of the firm of **WOODCOCK WASHBURN LLP**, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania 19103 as attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

David A. Cherry Reg. No. 35,099

______________________ Reg. No. ____________

Address all telephone calls and correspondence to:

David A. Cherry
WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone No.: **(215) 568-3100**
Facsimile No.: **(215) 568-3439**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Peter James Brian Lamb	Peter James Brian Lamb **Signature**
Mailing Address: 12 Clifford Avenue 1675 Irene ZAX South Africa	**Date of Signature:** December 5, 2001
City/State of Actual Residence: Irene, South Africa	**Citizenship:** South Africa

DOCKET NO. : ADMS-0003 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Peter James Brian LAMB

Serial No.: 10/031,860 **Group Art Unit:** not yet known

International Filing Date: 26 April 2000 **Examiner:** not yet assigned

For: DEVICE FOR DEPOSITING A NON-FLOWABLE OBJECT OR A NON-FLOWABLE MEDICAMENT IN A BODY CAVITY

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

ASSOCIATE POWER OF ATTORNEY

The undersigned, of the firm WOODCOCK WASHBURN LLP, One Liberty Place - 46th Floor, Philadelphia, Pennsylvania 19103, Attorney and/or Agents for Applicant(s), hereby appoints the following:

Richard E. Kurtz	Registration No. 19,263	Michael J. Swope	Registration No. 38,041
Dale M. Heist	Registration No. 28,425	Michael J. Bonella	Registration No. 41,628
John W. Caldwell	Registration No. 28,937	Harold H. Fullmer	Registration No. 42,560
Gary H. Levin	Registration No. 28,734	John E. McGlynn	Registration No. 42,863
Steven J. Rocci	Registration No. 30,489	Jonathan M. Waldman	Registration No. 40,861
Dianne B. Elderkin	Registration No. 28,598	Chad Ziegler	Registration No. 44,273
John P. Donohue, Jr.	Registration No. 29,916	Gwilym J.O. Attwell	Registration No. 45,449
Henrik D. Parker	Registration No. 31,863	David N. Farsiou	Registration No. 44,104
Suzanne E. Miller	Registration No. 32,279	Paul K. Legaard	Registration No. 38,534
Lynn B. Morreale	Registration No. 32,842	Steven H. Meyer	Registration No. 37,189
Mark DeLuca	Registration No. 33,229	Paul B. Milcetic	Registration No. 46,261
Joseph Lucci	Registration No. 33,307	Joseph R. Condo	Registration No. 42,431
Michael P. Dunnam	Registration No. 32,611	Michael K. Jones	Registration No. 41,100
Michael D. Stein	Registration No. 34,734	Frank T. Carroll	Registration No. 42,392
Albert J. Marcellino	Registration No. 34,664	Thomas E. Watson	Registration No. 43,243
David R. Bailey	Registration No. 35,057	Eric H. Vance	Registration No. 47,151
Doreen Yatko Trujillo	Registration No. 35,719	Peter M. Ullman	Registration No. 43,963
Barbara L. Mullin	Registration No. 38,250	Richard B. LeBlanc	Registration No. 39,495
Michael P. Straher	Registration No. 38,325	Joseph D. Rossi	Registration No. 47,038
Kevin M. Flannery	Registration No. 35,871	George J. Awad	Registration No. 46,528
Lynn A. Malinoski	Registration No. 38,788	Steven D. Maslowski	Registration No. 46,905
Steven B. Samuels	Registration No. 37,711	S. Maurice Valla	Registration No. 43,966
Janet E. Reed	Registration No. 36,252	Emma R. Dailey	Registration No. 48,491
Jeffrey J. King	Registration No. 38,515	Vincent J. Roccia	Registration No. 43,887
Robert B. Washburn	Registration No. 16,574	Robin S. Quartin	Registration No. 45,028
Norman L. Norris	Registration No. 24,196	Patrick J. Farley	Registration No. 42,524

Stephen C. Timmins	Registration No. 48,481	Richard D. Watkins	Registration No. P50,993
Erich M. Falke	Registration No. 49,049	Wendy A. Choi	Registration No. 36,697
Jane E. Inglese	Registration No. 48,444	Felicity E. Groth	Registration No. 47,042
Susan C. Murphy	Registration No. 46,221	Christine A. Goddard	Registration No. 46,731
Raymond N. Scott, Jr.	Registration No. 48,666	Andrew J. Hagerty	Registration No. 44,141
David L. Marcus	Registration No. 46,897	Scott E. Scioli	Registration No. 47,930
Lawrence A. Aaronson	Registration No. 38,369		
John A. Harrelson	Registration No. 42,637		
Sharon Fenick	Registration No. 45,269		
Daniel D. Biesterveld	Registration No. 45,898		
Phillip A. Singer	Registration No. 40,176		

his/her associates with full power to prosecute the above-identified application and to transact all business in the Patent Office connected therewith and requests that correspondence continue to be directed to the firm of WOODCOCK WASHBURN LLP at the above address.

Date:

David A. Cherry
Registration No. 35,099

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439